Development of Artificial Intrathoracic Circulatory Pumps*

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THE earliest successful laboratory attempts at replacing the heart with an artificial intrathoracic vascular pump were made by Kolff and Liotta.† Other investigators followed, each using a different design or approach. Some were complicated bulky devices with elaborate energizing and controlling systems. These experiments contributed much toward our understanding of many major problems encountered in this field. They, in fact, demonstrated heart replacement to be feasible.

Some of the reported complications encountered will be discussed to provide a better understanding of the over-all problem.

ATRIAL SUCTION

The original artificial heart models were made of a variety of materials, such as Lucite®, stainless steel and polyurethane [*3–17*]. These were patterned after bellows, rolling diaphragm, pistons and the like. When energized, the opening stroke (diastole) created a sudden high negative pressure which caused sucking of the atria and great veins. Several technics were devised to overcome this sudden high negative pressure. Electrical and mechanical timing devices were used to lengthen the diastolic filling period and compensatory elastic membranes were introduced into the systems to compensate for the sudden increase in ventricular volume and negative pressure [*18–21*].

† Some apparatus intended to be used for an artificial heart [*1,2*] was shown at the 1958 and 1959 A.S.A.I.O. meetings, but experiments were not attempted. In 1960 Kolff, W. J. and Liotta, D. independently obtained survival in dogs with the heart replaced by an intrathoracic prosthesis with the chest closed. We consider survival in this particular experimental situation when the dog regains spontaneous respiratory movements and the survival duration ends when it is impossible to maintain adequate spontaneous respiratory movements.

PULMONARY EDEMA AND PORTAL SEQUESTRATION SYNDROME

High peak pressures during systolic ejection and inequality of the minute volume output of each ventricle are the two main causes of blood sequestration. Pressure curves which show abnormally high peak pressures cause damage to the capillary bed and allow blood to sequestrate in the interstitial spaces [*22*].

With abolition of the reflexes which control cardiac output, a mechanical means becomes necessary to maintain equal ventricular stroke volumes. If the stroke volume of the right ventricle is 1 cc. more than that of the left and the rate is 80 per minute, in just five minutes the pulmonary circuit will be called upon to hold 400 cc. more blood than it does normally. Since the pulmonary reservoir does not have this capacity, frank pulmonary edema develops.

The minute volume output of each artificial ventricle will be equal if the output is equal to and dependent upon the input (that is, across a normal gradient). Kolff, Hastings and others have utilized pressure valves to solve this problem [*4,11*]. Later, Kolff et al. used a servomechanism and have reported good results

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[22]. The normal ventricle is an elastic chamber capable of accepting varying input volumes, and it is likely that this principle will be applicable in artificial ventricles fabricated from elastic material.

THROMBOSIS AND THROMBOEMBOLIC PHENOMENA

One of the most perplexing problems centers around our lack of basic understanding at the blood-plastic interface. When blood is allowed to flow through a tube of any foreign material, the surface of the tube is quickly coated with certain blood proteins. Perhaps the best demonstration of this phenomenon is to measure the zeta potential across the surface. As blood flows through the tube, the potential quickly drops to zero, having been insulated by the absorption of plasma proteins onto the surface. So far there is no sound explanation as to why this occurs, but it seems as if the blood wishes to cover all foreign material so it no longer "sees" it as foreign. Thrombocytes then stick to the surface as do fibrocytes. If the surface is smooth, this coating is not well anchored and breaks off as emboli. If the surface is rough, the process is progressive and forms a thrombus.

A surface-active agent, such as Zephiran Chloride®, has been used to bind heparin to the surface of plastics and has been successful in prolonging the surface clotting time. Other approaches are being attempted, such as cross linking certain non-ionic polymers to the surface, graphite coating of the surface, and addition of chemically bonded quaternary ammonium groups to the plastic surface.

Empiric approaches to this problem will be time-consuming and leave much to be desired as to our basic knowledge and understanding in this area. Perhaps enough interest can be generated so that hematologists, chemists and pathologists can work together in this perplexing area.

HEMORRHAGE FROM ANASTOMOTIC SITES

Although a purely technical problem, hemorrhage has caused many otherwise perfect experiments to end in disaster. Rigid tourniquet bracelets have been used by Liotta and Kolff to anchor the artificial ventricle to the atria. Sutures anchored to rigid sewing rings are invariably torn out by the unrelenting forces of the artificial ventricle. Padding the sewing ring to absorb the shock helps considerably, but is not totally satisfactory. Pressure polymerizing plastics (tissue adhesive) have so far had only a limited application.

RED CELL DESTRUCTION

Mechanical blood pumping devices so far designed and all of the currently used prosthetic valves cause hemolysis. Therefore, hemolysis becomes a major threat when a mechanical pumping device and four prosthetic valves are used simultaneously. Presumably this process could be brought into equilibrium provided the liver and bone marrow are capable of the necessary compensatory response. Better pump and valve designs are needed.

ACID-BASE IMBALANCE

This is a problem which is poorly understood. If perfusion pressure to the kidneys and liver has dropped below normal, the explanation is simple. An easy explanation can also be offered if there has been significant changes in pulmonary function. However, when these two circumstances do not exist, the cause is obscure. Kolff et al. believe this may be related to thromboembolic phenomena [22].

LACK OF DURABLE MATERIALS

The pliable materials used and tested for fabricating artificial hearts have shown fatigue fractures along the lines of stress. More durable materials are available, but these have other undesirable characteristics which discourage their usage.

INTERNAL POWER SUPPLY

Before an attempt is made to move the power supply inside the body, the problems of heat dissipation and limited power and storage volume must be solved.

EXPERIENCE IN THIS LABORATORY

Eight models of intrathoracic circulatory pumps have been designed and used in this laboratory. All have been constructed from Dacron® reinforced Silastic.®* Power transmission has been through an air energized system. For research purposes, this project was divided into two parts, each having two categories.

* Manufactured by the Dow-Corning Corp., Midland, Michigan.

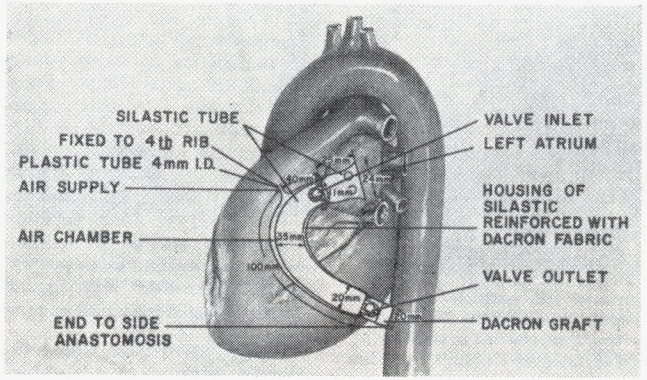
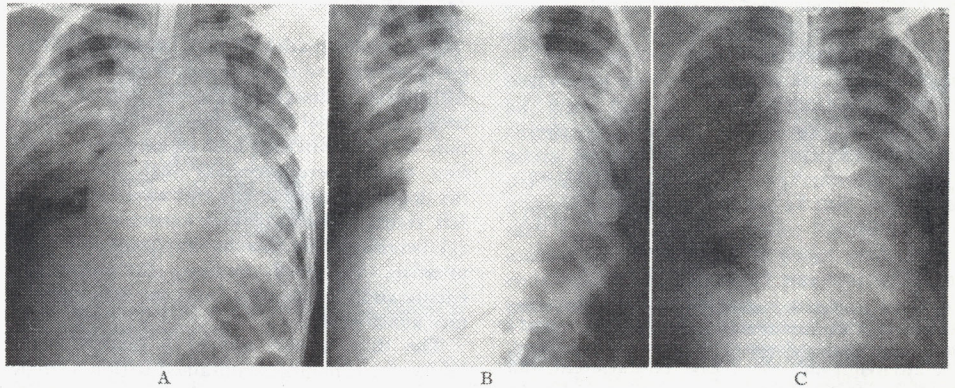


FIG. 1. Left ventricular bypass.



A B C

FIG. 2. A, chest roentgenogram after cardiac massage showing severe pulmonary edema. B, x-ray evidence of pulmonary edema clearing six hours after inserting artificial left ventricle. C, pulmonary edema cleared forty-eight hours after inserting artificial left ventricle.

I. Intrathoracic circulatory pumps
   A. Ventricular replacement
   B. Ventricular assistors
II. Power supply
   A. Externally powered systems
   B. Internally powered systems

The primary goal has been to duplicate the cardiac function in as many physiologic parameters as possible.

INTRATHORACIC CIRCULATORY PUMPS

The first model was designed as a partial left ventricular bypass. (Fig. 1.) The pump is actuated by compressed air being forced in between the double walls. The resulting collapsing of the inner wall forces the blood from the lumen. Unidirectional blood flow is accomplished by ball type valves which guard either end. The external air energizing system is triggered by the R wave of the electrocardiogram. Methods and results of this system have been previously reported [23–26].

The purpose for developing the intrathoracic left ventricular bypass pump was to bridge a gap in the treatment of acute left ventricular failure. Extracorporeal pumping systems have been used for this purpose, but require the use of heparin, which in the postoperative patient can lead to serious complications. This technic is also limited to relatively short periods of time as measured in hours. Use of the intrathoracic pump requires no heparin and the pump was designed to assist the circulation for

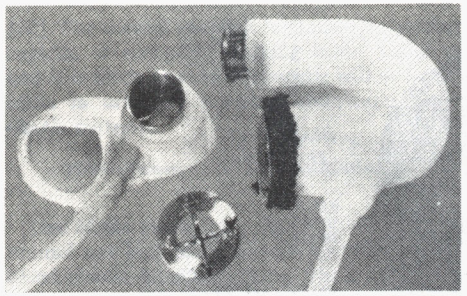


FIG. 3. Artificial right and left ventricles made of molded Dacron reinforced sheet Silastic. One of the atrioventricular valves has been removed to show bulging of inner tube during systole.

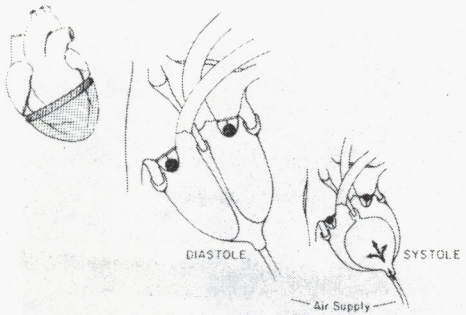


FIG. 4. Diagrammatic representation of ventricular replacement with intrathoracic pump. The animal's natural aortic and pulmonary valves have been utilized. The atrioventricular valves have been replaced with Silastic ball type valves.

several weeks, thus allowing ample time for recovery of ventricular function. After successful use in over 100 dogs, an opportunity arose in which we were able to try the bypass clinically. The following is a summary of the case history.

The patient (G. W.), a forty-two year old Negro man, was admitted in severe congestive failure. After several weeks of intensive medical management, the patient became compensated. Catheterization studies revealed a severe aortic stenosis and regurgitation. At this time he was considered a reasonable operative risk and on July 18, 1963, an aortic valve replacement (Starr-Edwards No. 8) was performed. Eighteen hours postoperatively, the patient had a cardiac arrest. The chest was immediately opened and the heart resuscitated. After this procedure, the patient showed signs of damage to the central nervous system, renal failure and rather promptly went into refractory left ventricular failure (evidenced by severe pulmonary edema). Because of the hopelessness of the situation, the patient was considered to be an ideal candidate for left ventricular bypass. On July 19, 1963, one of the experimental models of the artificial left ventricle was placed in the patient. Both clinically and radiographically, pulmonary edema subsided (Fig. 2A, B and C), respiration deepened and neurologic signs improved. The patient remained anuric and peritoneal dialysis was started on July 22, 1963. After nearly four days of continuous left ventricular support, the patient died although the artificial left ventricle remained functional. Postmortem examination showed chronic damage to the liver, lungs and kidneys, probably related to long-standing decompensation.

To our knowledge this represents the first attempt with an implantable artificial ventricle in a human subject. A human model has since been designed and is now awaiting clinical trial.

The second model (Fig. 3) was designed to provide complete replacement of the ventricles. Although the design is different, it is identical to the first model in principle. Surgical extirpation of the ventricles and replacement of all four valves were necessary with this model. Six dogs were used to test this model with only fair results. The problems encountered were: (1) bending of the tube by diaphragmatic compression, (2) atrial suction, (3) pulmonary edema and (4) bleeding from the atrioventricular anastomosis.

The third model was of a saccular type having two chambers contained within a single housing. The aortic and pulmonic valves were spared, replacing only the mitral and tricuspid with ball valve prostheses. After a single trial this was modified to a fourth model (Fig. 4 and 5A) which was similar except that blood displacement of both ventricles was accomplished by a single air chamber contained within the septum. Ventricular output was dependent upon input, and imbalance of the ventricles was not a problem.

Bleeding from the atrioventricular anastomosis continued to be a major problem. A solution was found by adding an outer cuff to the artificial ventricle. After completing the anastomosis, the cuff was rolled down over the suture line. This controlled the bleeding by simple tamponade. (Fig. 5B.)

A more appealing solution to this problem was to leave all existing anatomic structures in place and simply add a pumping device. For this reason a fifth model (Fig. 6) was made consisting of two flat Silastic balloons. One balloon was placed in each ventricle through two small ventriculotomies. When inflated (systole), blood was forced from each ventricle by simple volume displacement. Selecting the correct location for placement became a critical problem. More often than not the balloons interfered with the valve leaflets, chordae tendinae and papillary muscle function.

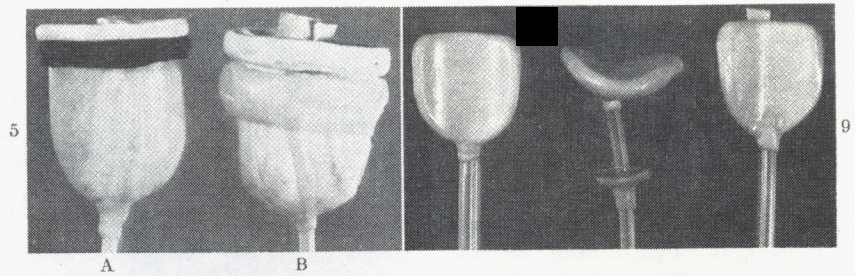


FIG. 5. A, third model shown on left. B, fourth model on right shows the addition of cuff.

FIG. 6. Silastic balloons molded to fit inside the right and left ventricles.

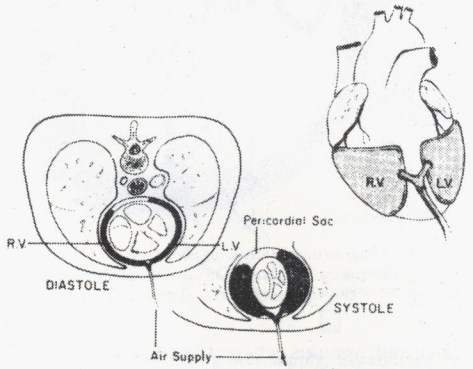


FIG. 7. Intrapericardial assistor showing the assistor in place. Cross sectional view.

These balloons were later modified to function within the pericardial cavity. (Fig. 7, 8 and 9.) With the heart in fibrillation, adequate circulatory function was maintained for four hours. At the end of this period, the heart was defibrillated and the balloons removed. Usually a single electrical shock was all that was necessary to revert the ventricular fibrillation to a normal sinus rhythm. The major problem encountered with this model was tearing of the pericardium due to recoil.

The seventh model was made by further modifying the balloons to operate extrapericardially. (Fig. 10.) A sheet of Silastic slightly larger than the balloons was placed over the balloons and sutured to the pericardium. Again, adequate circulatory function was possi-

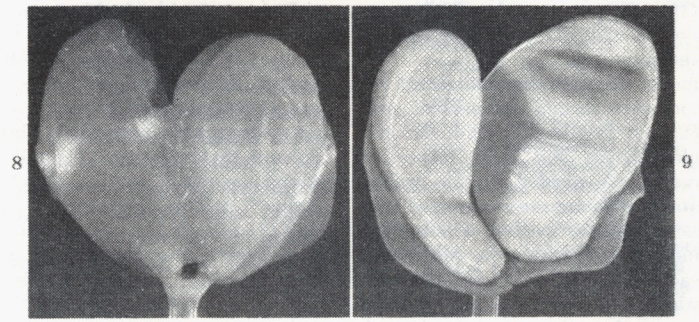


FIG. 8. Intrapericardial assistor, external view.

FIG. 9. Intrapericardial assistor, internal (epicardial) view.

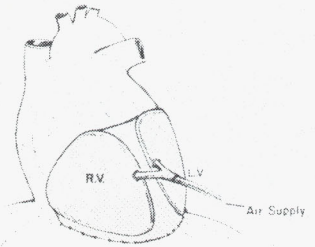


FIG. 10. Extrapericardial assistor showing fixation to pericardium along the diaphragmatic reflexion.

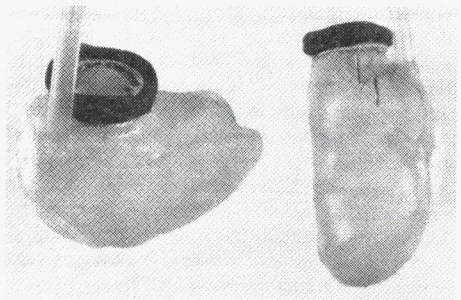


FIG. 11. Right and left intraventricular pumps having incorporated atrioventricular ball valves.

ble even with the heart in fibrillation. This model gave the added protection of the lubricating surface offered by the pericardium. When inserting the last two models, it was not necessary to use the pump oxygenator. The systolic period of these last two models could be synchronized with the heart's systolic phase by triggering with the R wave of the electrocardiogram. In this manner it became an assistor. As before, pericardial tearing caused all the failures that occurred.

The last model designed for total heart replacement combines certain features of previous models. It is necessary to remove only atrioventricular valves and their respective papillary muscles. A molded double walled Dacron reinforced Silastic sac is dropped into each ventricle through respective atriotomies. Each sac is molded to fit within the ventricular cavity and each has an incorporated atrioventricular prosthetic ball valve. (Fig. 11.) The air energizing tube is brought out through each atrial appendage. (Fig. 12.) The only suture attachment necessary is at the mitral and

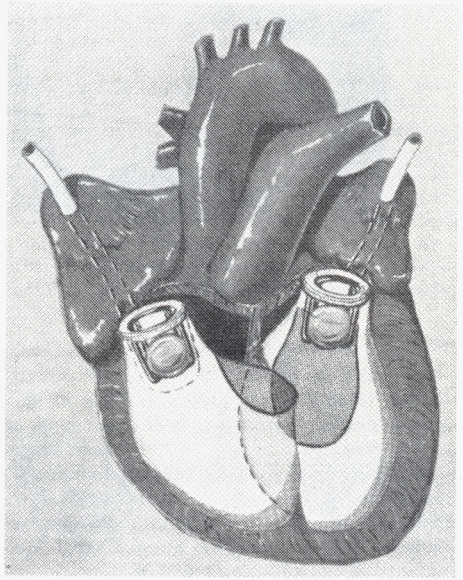


FIG. 12. Diagrammatic drawing showing the two intraventricular pumps in place. The air energizing tubes are brought out through each atrial appendage.

tricuspid annulus where the prosthetic valves are secured. After evacuating the air and closing the two atriotomies, the artificial ventricles are ready to be energized with the air power supply. Twelve hour survivors have been obtained with this model. Cerebral edema has occurred in six of these animals, the cause of which is still obscure.

POWER SUPPLY

Power transmission by an air energized system has been found to be the most adaptable method thus far investigated. Air is easily controlled, lightweight, relatively frictionless and has almost no inertia. Four types of external air systems have been used. Three were of the "closed system" type: (1) rolling diaphragm pump operated by an electric motor, (2) Teflon® bellows operated by compressed air and (3) Silastic bellows operated by an electrically driven cam. The fourth type was of the "open system" variety which utilized compressed air allowed to pulsate through solenoid valves.

To date all of the models just described have been dependent upon an extracorporeal power

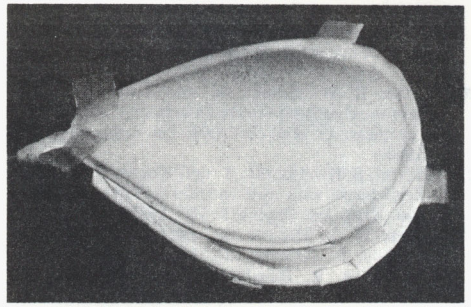


FIG. 13. Silastic bellows to be mounted either upon or within the thoracic cage. A single spring wire around the edges forms the framework.

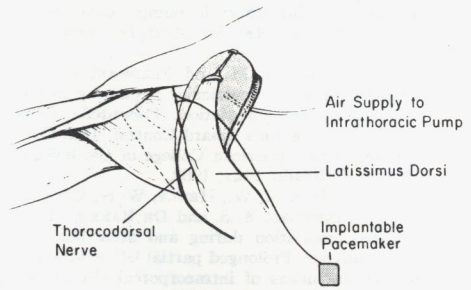


FIG. 14. Intracorporeal power supply. Silastic bellows affixed to chest wall. Dotted line indicates normal insertion of latissimus dorsi muscle. Operation of bellows is dependent upon contraction of latissimus dorsi, which is controlled by implantable pacemaker.

supply necessitating one or two tubes being brought out through the chest wall. We have done some investigation on utilizing skeletal muscle as the source of power. The insertion of the latissimus dorsi muscle was detached and connected to a Silastic bellows, molded to fit the chest wall. Terminals from a pacemaker then were connected to the thoracodorsal nerve. (Fig. 13 and 14.) When the thoracodorsal nerve is stimulated with the pacemaker (using a rectangular pulse of 5 volts intensity, frequency of 20 cycles per second and duration of 2 milliseconds), the latissimus dorsi muscle contracts. This forces air from the bellows into the artificial heart displacing the blood contained within the ventricles (systole). Between shocks the muscle relaxes and the bellows, which is spring loaded, expands. A slight negative pressure develops within the bellows which allows the air from the ventricle to be pushed back into the bellows by the volume of blood received from the atria (diastole). The power developed from this arrangement appears adequate for the purpose and has encouraged further investigation in this direction.

COMMENTS

Due to obvious needs for refinement in each model, no long-term survivals have been attempted. After a particular problem became evident and studied, the animals were sacrificed. A few were allowed to live for periods up to twelve hours.

From experience gained in the laboratory, it has been shown that both ventricular replacement and ventricular assistors are quite feasible. There is a great need for both, evident from the fact that heart disease, uncorrectable by present medical or surgical methods of treatment, account for more deaths than any other disease in this country. There are good reasons to believe that replacement of the heart for such conditions by an artificial heart is feasible. To achieve this objective, however, certain problems having both physiologic and engineering aspects remain to be solved. None of these are considered insurmountable.

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